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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/694,103	10/27/2003	James F. Zucherman	5910-189	3095

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MEDTRONIC
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EXAMINER	
SWIGER III, JAMES L	

ART UNIT	PAPER NUMBER
3775	

MAIL DATE	DELIVERY MODE
06/11/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/694,103	ZUCHERMAN ET AL.	
	Examiner	Art Unit	
	JAMES L. SWIGER	3775	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 March 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-67* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-67* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *27 October 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *5/6/2009*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims **1, 3-4, 6-10, 12, 14-20, 23, 26-27, 29-31, 33-36, 62, 64-67** are rejected under 35 U.S.C. 103(a) as being unpatentable over Zucherman et al. (US Patent 6,048,342) in view of Brantigan (US Patent 4,834,757) and Branch et al. (US Publication 2002/0016592) and Carter (US Patent 4,863,470) OR Crickenberger et al. (US Patent 5,728,128).

Zucherman et al. disclose an implant capable of being placed between spinous processes having a body (902), a spacer (1016) capable of rotation on a shaft. Note that spokes 1020 do not necessarily *prevent* rotation, but merely help the spacer to fit better (See Col. 23, lines 15-37). Zucherman et al. also disclose a tissue expander (1010) extending from the shaft. Zucherman et al. also disclose a spacer that has a cross-sectional shape that may be considered oval-shaped (see Fig. 93a), has a dimension that could be 8 or 10mm (see table in Column 20), and wherein the tissue expander has a generally increasing cross section as it approaches wing 1032. The spacer is also connected at an attachment (1014) and the attachment includes a device for receiving a wing (1034), and a first wing (1032). The shaft includes an attachment to

which the tissue expander is molded (see Fig. 92a). The spacer (1016) is located between a first wing (1032) and a second wing (1004), and see Fig. 92b. Zucherman et al. also disclose an outer spacer (1016) and an inner spacer (1002) capable of being rotatable with one another, as noted above. Also the spacers' structure may be considered have flattened or slightly radiused upper and lower surfaces (see profile in Fig. 93a), and rounded edges.

Zucherman et al. disclose the claimed invention except for a tissue expander being radiolucent. Brantigan '757 teaches the incorporation of radiolucent material for improved X-ray visualization of the device (see col. 1, lines 31-36). The spacer is also capable of being at least partially radiolucent, and would allow a T-shape combined with a radiopaque wing. It would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the device of Zucherman et al. '342 having at least a partially radiolucent portion in view of Brantigan '757 to better allow the device to be seen during surgery in the presence of X-ray.

The combination of Zucherman '342 in view of Brantigan '757 disclose the claimed invention except for a portion that is at least partially radiopaque. Branch et al. '592 disclose a fusion device that is at least partially radiopaque that allows a means for viewing placement of the implant via radiography during surgery. (See par 0009). It would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the device of the combination of Zucherman et al. '342 in view of Brantigan '757 having at least a portion radiopaque in view further of Branch '592 to allow the device to be better viewed in surgery.

Zucherman et al. '342 in view of Brantigan '757 and Branch '592 (hereafter "ZBB") disclose the claimed invention. However, it is further noted that the claims are further rejected in view of Carter OR Crickenberger et al. ZBB disclose the claimed invention except for specifically pointing out where the implant is made of a combination of materials. It is noted that use of radiopaque and radiolucent materials is well known in the art for providing improved visualization when doing surgery in combination with some form of imaging or fluoroscopic technique. Carter discloses an implant. The implant is mostly radiolucent, but to help in visualizing the location of the implant, a radiopaque identification marker is placed within it. (see Abstract for quick reference) Use of BOTH materials is known in the art to assist in visualizing the implant during surgery. Regarding Crickenberger et al., Crickenberger teaches an implant (13) having a stem which is radiolucent which further has a radiopaque angle locator wire located within it. Both materials are disposed together to assist in visualization during surgery. See Abstract for quick reference. It is further noted that in a patent to Arroyo (US Patent 4,837,279), Arroyo teaches a bone cement or implant. Arroyo also teaches that polymers are known in the art to be radiolucent--similarly to applicant's claimed invention. However, since it is hard to see a radiolucent material, "opacifiers" or radiopaque materials are added to the cement or implant to help identify it's location or placement. (See also Col. 1, lines 28-42). In a similar way, it would be obvious to combine both radiopaque or radiolucent materials to help assist with visualization of an implant during placement in surgery. Thus, it would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the device of

ZBB to incorporate the teachings of Carter OR Crickenberger et al. to enable a surgeon to better visualize the device.

Further, ZBB disclose the claimed invention except for the combination of radiolucent and radiopaque materials. It would have been obvious to one having ordinary skill in the art at the time the invention was made to construct an implant having radiopaque and radiolucent materials, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. In re Leshin, 125 USPQ 416.

Claims **2, 13, 21-22, 37, 39-41, 43-46, 47-50, 53-55, 57-61, 63** are rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Zucherman et al. (US Patent 6,048,342) in view of Brantigan (US Patent 4,834,757) and Branch et al. (US Publication 2002/0016592) and Carter (US Patent 4,863,470) OR Crickenberger et al. (US Patent 5,728,128) as applied to claims 1, 19, and 62 above, and further in view of Brantigan '327.

Zucherman et al. (US Patent 6,048,342) in view of Brantigan (US Patent 4,834,757) and Branch et al. (US Publication 2002/0016592) and further in view of Carter (US Patent 4,863,470) OR Crickenberger et al. (US Patent 5,728,128) disclose the invention described *supra* except for wherein the tissue expander and the spacer may be made at least in part of polyetherketone. Brantigan '327 teaches the use of a preferred polyether ketone in implants (see Col. 3, lines 9-15). It would have been obvious to one having ordinary skill in the art at the time the invention was made to

construct the device of the combination of Zucherman '342, Brantigan '757 and Branch et al. '592 and further in view of Carter or Crickenberger having at least a tissue expander or spacer made at least partially of polyether ketone in further view of Brantigan '327 to be able to view the device and also so that it has optimum biocompatibility once implanted.

Claims **5, 28, and 42** are rejected under 35 U.S.C. 103(a) as being unpatentable over Zucherman et al. (US Patent 6,048,342) in view of Brantigan (US Patent 4,834,757) and Branch et al. (US Publication 2002/0016592) and Carter (US Patent 4,863,470) OR Crickenberger et al. (US Patent 5,728,128) as applied to claims 1 and 19 above, and further in view of Zucherman et al. (US Publication 2001/0012938). Zucherman et al. (US Patent 6,048,342) in view of Brantigan (US Patent 4,834,757) and Branch et al. (US Publication 2002/0016592) and further in view of Carter (US Patent 4,863,470) OR Crickenberger et al. (US Patent 5,728,128) teach the claimed invention except for a spacer having an off-center bore. Zucherman et al. '938 disclose a spacer with an off-center bore so that it may be positioned relative to the central body of the implant (see claim 15). It would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the device of the combination of Zucherman et al. (US Patent 6,048,342) in view of Brantigan (US Patent 4,834,757) and Branch et al. (US Publication 2002/0016592) and Carter (US Patent 4,863,470) OR Crickenberger et al. (US Patent 5,728,128) having at least an off-center bore in view of Zucherman et al. '342 to better orient the spacer in relation to the implant.

Claims **56** is rejected under 35 U.S.C. 103(a) as being unpatentable over the

combination of Zucherman et al. (US Patent 6,048,342) in view of Brantigan (US Patent 4,834,757) and Branch et al. (US Publication 2002/0016592) and Carter (US Patent 4,863,470) OR Crickenberger et al. (US Patent 5,728,128) and Brantigan '327 as applied to claim 47 and in further view of Zucherman et al. (US Publication 2001/0012938). The combination of Zucherman et al. (US Patent 6,048,342) in view of Brantigan (US Patent 4,834,757) and Branch et al. (US Publication 2002/0016592) and Carter (US Patent 4,863,470) OR Crickenberger et al. (US Patent 5,728,128) and Brantigan '327 teach the claimed invention except for a spacer having an off-center bore. Zucherman et al. '938 disclose a spacer with an off-center bore so that it may be positioned relative to the central body of the implant (see claim 15). It would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the device of the combination of Zucherman et al. (US Patent 6,048,342) in view of Brantigan (US Patent 4,834,757) and Branch et al. (US Publication 2002/0016592) and Carter (US Patent 4,863,470) OR Crickenberger et al. (US Patent 5,728,128) and Brantigan '327 having the off center bore in view of Zucherman et al. (US Publication 2001/0012938) to better orient the spacer in relation to the implant.

Claims **11, 24-25, and 32** are rejected under 35 U.S.C. 103(a) as being unpatentable over Zucherman et al. (US Patent 6,048,342) in view of Brantigan (US Patent 4,834,757) and in view of Branch et al. (US Publication 2002/0016592) and further in view of Carter (US Patent 4,863,470) OR Crickenberger et al. (US Patent 5,728,128). Zucherman et al. (US Patent 6,048,342) in view of Brantigan (US Patent 4,834,757) and Branch et al. (US Publication 2002/0016592) and Carter (US Patent

4,863,470) OR Crickenberger et al. (US Patent 5,728,128) teach the claimed invention except for an implant resembling specific shapes under X-ray. While the shape under x-ray is generally depending upon the structure of the actual implant, particular placement of radiolucent and radiopaque materials makes the actual structure irrelevant, as these materials control what passes through. Further it would have been an obvious matter of design choice to one skilled in the art at the time the invention was made to construct the device with either the implant having a certain shape, or placing the opaque/lucent materials strategically to form a particular shape, since applicant has not disclosed that such solve any stated problem or is anything more than one of numerous shapes or configurations a person ordinary skill in the art would find obvious for the purpose of identifying or confirming a location of an implant during surgery or after surgery. In re Dailey and Eilers, 149 USPQ 47 (1966).

Claims **38, and 21-52** are rejected under 35 U.S.C. 103(a) as being unpatentable over Zucherman et al. (US Patent 6,048,342) in view of Brantigan (US Patent 4,834,757) and Branch et al. (US Publication 2002/0016592) and Carter (US Patent 4,863,470) OR Crickenberger et al. (US Patent 5,728,128) as applied to claims 1, 19, and 62 above, and further in view of Brantigan '327. Zucherman et al. (US Patent 6,048,342) in view of Brantigan (US Patent 4,834,757) and Branch et al. (US Publication 2002/0016592) and Carter (US Patent 4,863,470) OR Crickenberger et al. (US Patent 5,728,128) as applied to claims 1, 19, and 62 above, and further in view of Brantigan '327. teach the claimed invention except for an implant resembling specific shapes under X-ray. While the shape under x-ray is generally depending upon the

structure of the actual implant, particular placement of radiolucent and radiopaque materials makes the actual structure irrelevant, as these materials control what passes through. Further it would have been an obvious matter of design choice to one skilled in the art at the time the invention was made to construct the device with either the implant having a certain shape, or placing the opaque/lucent materials strategically to form a particular shape, since applicant has not disclosed that such solve any stated problem or is anything more than one of numerous shapes or configurations a person ordinary skill in the art would find obvious for the purpose of identifying or confirming a location of an implant during surgery or after surgery. In re Dailey and Eilers, 149 USPQ 47 (1966).

Response to Arguments

The reemergence of claim 42 is acknowledged; the action has been changed to reflect this claim.

Applicant's arguments filed 3/6/2009 have been fully considered but they are not persuasive. With regards to applicant arguments, it is noted that the claimed invention still reads on the prior art of record. With regards applicant's position of Zucherman, Branch and Brantigan, the examiner respectfully disagrees. Applicant continues to argue the limitations presented previously in the Appeal brief filed 6/24/2008. In view of the new teachings under Carter or Crickenberg that further modify Zucherman, Branch and Brantigan, applicant argues that these references do not remedy the failure to establish obviousness, that these references do not disclose elements that are able to perform multiple functions. It is noted however, that in claim 1, that it is at least the tissue expander that performs one of the intended functions of the claimed invention,

along with the shaft. Each element has further functional limitations due to the nature of the device. Each of those elements has a material property, namely being made in part of a radiolucent or radiopaque material, respectively, that have dependent functions with respect to the device. The claim does not appear to give life to the materials themselves independently, giving them "multiple functions." For example, the tissue expander is in part at least radiolucent, which has the functionality of "not impairing the ability to view the spinous process during x-ray." However, this function is a dependent function of the tissue expander, as the tissue expander's use is critical before any radiolucent material becomes relevant during a surgical procedure. In at least this example, the material property would be obvious to one having ordinary skill in the art as necessary in a procedure of this type, and has a singular function with respect to the rest of the device.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JAMES L. SWIGER whose telephone number is (571)272-5557. The examiner can normally be reached on M-F 9-530.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thomas Barrett can be reached on 571-272-4746. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/JAMES L. SWIGER/
Examiner, Art Unit 3775

/Thomas C. Barrett/
Supervisory Patent Examiner, Art Unit 3775